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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/534,280 HERZ, RACHEL S Office Action Summary Examiner Art Unit Kevin S. Orwia 1611 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 24 November 2008. 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-23 is/are pending in the application. 4a) Of the above claim(s) 19-23 is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 1-18 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10)⊠ The drawing(s) filed on <u>06 May 2005</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

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DETAILED ACTION

Status of the Claims

Claims 1-23 are currently pending. Claims 1-18 are the subject of this Office Action. This is the first Office Action on the merits of the claims. Non-elected claims 19-23 are withdrawn from consideration.

Election/Restrictions

Applicant's election of Group II (claims 1-18) in the reply filed on Nov. 24, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 19-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Abstract

The abstract of the disclosure is objected to because the abstract does not conform to current USPTO guidelines for the preparation of patent abstracts. While the current abstract is acceptable in its general content, the abstract is over the 150 word limit set by the USPTO. Applicant is reminded of the proper language and format for an abstract of the disclosure. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided

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for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details. The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns." "The disclosure defined by this invention." "The disclosure describes." etc.

A new abstract (150 words or less) is required that is sufficiently detailed as to provide general information about the precise nature of the invention to which the claims are directed. New matter is not permitted in the revised abstract. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112 (1st Paragraph)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for dissociating negative side effects from intake of a medication, does not reasonably provide enablement for preventing the development of taste and/or odor aversion. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ 2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

- 1) the nature of the invention;
- 2) the scope or breadth of the claims;
- 3) the state of the prior art;
- 4) the predictability or unpredictability of the art;
- 5) the relative skill of those skilled in the art;
- 6) the presence or absence of working examples;
- 7) the amount of direction or guidance presented and,
- 8) the quantity of experimentation necessary.

The relevant factors are addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

Firstly, per the restriction requirement dated Nov. 7, 2008, the invention of elected Group II has been construed to be a method of administering multiple individual doses of a drug. Applicant acknowledged this interpretation in the reply dated Nov. 24, 2008 (see top paragraph on page 2 of the reply) and has elected Group II without traverse

Scope or breadth of the claims: Instant claims recite:

[&]quot;[A method]...comprising administering multiple individual dosage units of the medication in a treatment regimen in a manner that prevents the development of taste- and/or odor aversion by preventing a patient from forming an explicit association between a particular color/flavor/odor of the medication and a negative response outcome."

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However, the instant specification as originally filed lacks adequate guidance, direction or discussion to apprise the skilled artisan of how to prevent the development of such aversion(s). The claims are broad in that they claim a method for *preventing* the development of taste and/or odor-aversion, the breadth of which exacerbates the complexity of the invention. The term "preventing" is a potent and absolute term indicating that the method will necessarily prevent the development of <u>any</u> taste- and/or odor-aversion, regardless of the cause, and in every instance following practice of the claimed method. Since the instant specification provides no limiting definition of the terms "prevent[s]" the term has been interpreted expansively. The term "prevent" encompasses a wide range of situations, from preventing a condition (i.e. aversion) from developing (i.e. occurring) to preventing it from progressing. Nor is the term limited by any time frame.

Applicant is claiming a method for preventing taste- and/or odor-aversion. The act of preventing embraces complete 100% inhibition. Thus, the burden of enablement in the assertion of prevention is much higher than would be the case of enabling, for example, simply the treatment of these aversions. As for the instant application in relation to the prior art, neither the prior art nor the instant application enable for prevention of taste and/or odor aversions. Nowhere in the instant application has the efficacy of the elected method been enabled to prevent the occurrence of taste and/or odor aversions. No data have been supplied to support this claim. Since absolute success in preventing most diseases/conditions is not reasonably possible, the specification, which lacks an objective showing that the claimed aversion conditions can

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actually be prevented, is viewed as lacking an adequate written description of the same.

The claims are thus extremely broad insofar as the claim language indicates that

following practice of the drug administration regimen of the claimed method, one will not

experience taste- and/or odor-aversion; that should one already have taste- and/or

odor-aversion, it will not worsen; and that it will not recur at any time following the

odor-aversion, it will not worsen, and that it will not recur at any time following the

administration of the treatment regimen.

State of the prior art: While the phenomena of taste- and/or odor-aversion, are well

known, the state of the art with regard to the underlying mechanisms of these conditions

are not well understood. The state of the art regarding the prevention of taste- and/or

odor-aversion is essentially non-existent. Examples demonstrating prevention of these

aversions have not been described in the art.

Degree of predictability or unpredictability in the art: It is clear that there is a

significant psychological component to the development of taste- and/or odor-aversion, $% \left(1\right) =\left(1\right) \left(1\right) \left$

which is a learned, or conditioned response that is not completely understood (see

Bernstein, pages 131-132, section entitled Food Aversion Learning). Furthermore,

studies have indicated that strong aversions to novel taste cues could be acquired in a

single learning trial, that is after one pairing of the conditioned stimulus (i.e. the taste)

and the unconditioned stimulus (i.e. the negative response outcome) (Bernstein, last

paragraph on page 131). This teaching alone demonstrates that taste aversion cannot

be prevented according to the method instantly claimed (i.e. with a large variety of

flavors), since even one pairing of a flavor with an adverse response can cause

aversion. Furthermore, evidence indicates that humans are predisposed to acquire

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aversions to foods which are eaten before episodes of illness or nausea (Bernstein, page 132, last full paragraph). As the ordinary artisan would appreciate, it is not practically possible to predict when a person will become ill or nauseous, thus the relevant art is unpredictable. Since every episode of illness or nausea which one might experience cannot be predicted, one could develop a food aversion due to illness or nausea following, but independent of, the instantly claimed treatment regimen. Bernstein further teaches that people can develop food aversions as a result of the coincidental association between consumption of a food and negative events, and that these aversions defy cognition (Bernstein, page 132, last full paragraph). Thus, the relevant art is clearly unpredictable. The claimed method cannot be enabled for preventing all taste- and/or odor-aversion events, which is currently within the scope of the claims.

Relative skill possessed by those in the art: In view of the discussion of the state and predictability of the prior art, and the scope of the claims, which are drawn to a method of preventing taste- and/or odor-aversion, the level of skill in the art is high and is at least that of a medical doctor or Ph.D. scientist with several years of experience in the field(s) of behavioral psychology and/or clinical addiction research.

<u>Presence or absence of working examples:</u> No working examples of preventing taste- and/or odor-aversion were provided.

Amount of guidance or direction provided: No guidance is presented in the specification as to how one could practice the claimed method to prevent taste- and/or odor-aversion. Thus, in the absence of such guidance in the specification, the ordinary

artisan would not know how to use the method to prevent the development of these aversions.

Quantity of experimentation required to make and use the invention: In view of the factors discussed above, the state of the art with regard to preventing taste- and/or odor-aversion in general is fairly complex and sufficiently unpredictable such that the skilled artisan would have been required to undertake undue experimentation to determine the exact conditions and manner and/or process of execution to arrive at those conditions amenable to actually preventing taste- and/or odor-aversion in the absence of detailed guidance to this effect. Absent such direction or guidance as to how the skilled artisan would go about preventing taste- and/or odor-aversion, one of ordinary skill in the art would have no alternative recourse but to undertake an exhaustive, and, thus, unduly burdensome search of methods to practice the claimed invention.

Claim Rejections - 35 USC § 112 (2nd Paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1-18 are indefinite in the recitation "A drug dispensing arrangement...comprising administering..." in claim 1. Per the restriction requirement

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dated Nov. 7, 2008, the invention of elected Group II has been construed to be a method of administering multiple individual doses of a drug. However, as written, the claims are drawn to a product, namely a drug dispensing arrangement. It is noted that a "drug dispensing arrangement" is defined as "a means for distributing, or dispensing a course of medication in a prescribed treatment regimen, or as part of a treatment regimen..." in paragraph [0023] of the specification. This definition could be taken to mean either a product or a method. The examiner suggests amending the claim language to recite "A method for dissociating negative side effects from the intake of a medication comprising..." or similar claim language consistent with the recited active method steps.

B) Claims 1-18 are indefinite in the recitation "...a manner that prevents the development of taste- and/or odor-aversion by preventing a patient from forming an explicit association between a particular color/flavor/odor of the medication and a negative response outcome" in claim 1. Neither the specification nor the claim sets forth the criteria that define "...a manner that prevents the development of taste- and/or odor-aversion..." The ordinary artisan would not have an objective measure of what such a manner encompasses. Furthermore, the ordinary artisan would have no objective measure of what an "explicit association" is, and no way to measure objectively whether such an explicit association has formed even if such a definition could be ascertained. None of these features are adequately defined in the instant specification or claims.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior at are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- Determining the scope and contents of the prior art.
- Ascertaining the differences between the prior art and the claims at issue.
- Resolving the level of ordinary skill in the pertinent art.
- Considering objective evidence present in the application indicating obviousness or nonohyiousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-14, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over BERNSTEIN (Bernstein, I. L. Proceedings of the Nutrition Society (1994), 53, 131-137) in view of THOMPSON (Thompson, J. E. A Practical Guide to Contemporary Pharmacy Practice. 1998; p. 20.1-20.6) and ALEXANDER

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(WO 02/26078; Published Apr. 4, 2002; 3rd foreign reference on IDS dated Dec. 3, 2008).

- 1. It is well-known in the art that aversions acquired to one food or taste (i.e. flavor) will often lead to avoidance of foods that share similar taste properties (Bernstein, page 136, middle of the paragraph). Bernstein teaches that learned aversions can arise during the course of a chronic illness (page 134, last paragraph). Bernstein teaches that the variety of diet is an important parameter in the development of food aversions. particularly during chronic illness, and that frequent changes in diet attenuate the effects of food aversions because as foods became aversive they would promotly be replaced by new ones. Frequent diet changes in a rat model of food aversion led the rats to consume significantly more food than those presented with only a single (initially highly palatable) food (page 135, last full paragraph). Bernstein teaches that both taste and odor are involved in the development of aversion (page 133, first two paragraphs under the heading Nature of the Conditioned Stimulus; page 134, top paragraph), and that both foods and beverages (i.e. liquids) can trigger similar aversion responses (page 135, last paragraph). Furthermore, Bernstein teaches that people with diverse diets are buffered against the effects of learned food aversions (page 136, middle of paragraph). Since Bernstein establishes that taste and odor are involved aversion responses to foods and beverages, the ordinary artisan would readily recognize that providing a variety of flavors would minimize the development of taste- and/or odor-aversion.
- It is also well-known in the art that flavors and colors are added to oral dosage forms to improve patient acceptance of the drug preparation (see Thompson, page

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20.1, subheading **B**; page 20.3, subheading **B**). Thompson teaches that flavors may be added to improve palatability or to mask the unpleasant taste of an active ingredient (page 20.3, subheading **B.1**; page 20.4, subheading **D.2**). Thompson teaches that determination of colors and flavors is best done empirically, and that flavor preference is not only age-related, but a matter of personal preference (page 20.3, **B.2**, **B.3.a.**, and **B.3.b**). Additionally, Thompson teaches that scents (i.e. odors) may be added to topical drug preparations to improve their aesthetic appeal (page 20.5, under Scents). One of ordinary skill in the art would recognize that topical preparations encompass transdermal (i.e. parenteral) drug preparations that are applied topically.

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3. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to provide a dosage regimen to a patient comprising multiple doses with a variety of flavors and colors, to provide a dosage regimen that minimizes the likelihood of taste aversion per the teachings of Bernstein and improves the acceptability to the patient as taught by Thompson. One would have been motivated to do so since Bernstein teaches that frequent changes in diet (i.e. flavor) buffer the development of food aversion and since Thompson teaches that colors and flavors are a matter of personal preference that improves the acceptability of a dosage form to the patient. Further, it is well within the skill of the ordinary artisan to empirically determine the best flavors, colors, form, and route of administration in view of the specific patient to be treated, their particular condition, and the length of time required for the dosage regimen. Therefore if an artisan wanted to treat a chronic illness in a patient, requiring a long dosage regime of a non-palatable

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drug, one would have been motivated to use a variety of flavorings, colors, and/or odors

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to make the regimen more acceptable and prone to less taste aversion as taught by

Bernstein and Thompson.

4. While it is the examiner's position that the skilled artisan would associate

randomness and/or unpredictability with the diversity of diet/flavors taught by Bernstein,

and would immediately envisage the presentation of a variety of flavors in a random

order, such arrangements were known in the art at the time of the invention. For

example, Alexander discloses an oral hygiene system comprising unit doses of multiple

flavors of toothpaste in the form of, inter alia, beads, tablets, and capsules (i.e. pills)

(abstract; page 2, last paragraph). This system is designed, in particular, for increasing

children's desire to brush their teeth (i.e. to increase compliance by preventing taste

aversion) (abstract; page 5, first paragraph; page 7, first paragraph; page 18, element

11), but is useful with medicated tablets as well (page 15, under element 3). Alexander

teaches that the flavor and color of the unit dosages can be varied and that ranges of

flavors may be offered (abstract; page 7, first paragraph; page 13, second paragraph),

particularly within one package (page 16, element 4). Alexander teaches that the beads

may be packaged in standard blister packs and can be available in a random pattern

(i.e. as from a mixed bag) (page 16, under element 3). Since Alexander is concerned

with providing a suitable packaging regime to increase compliance, it would have been

obvious to the ordinary artisan to arrange a variety of flavored/colored doses within the

packaging system taught by Alexander. Thus, claims 1, 2, 6, 7, and 9-14 are obvious

over Bernstein, Thompson, and Alexander.

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5. Flavor coated tablets (i.e. drug depots) are well known in the art, and formulation of the unit dosages would have been obvious to the ordinary artisan. For example, Alexander teaches beads, capsules, and tablets (i.e. solid drug depots) with taste-attractive crusts or skins, wherein the skin of each capsule holds the majority of the flavor for each unit dose (page 10, element 3 at the bottom of the page to page 11, top paragraph). Thus, it would have been obvious to the ordinary artisan to formulate the unit dosages with flavored coatings, rendering claims 3-5 obvious.

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- 6. Regarding claim 8, as stated above, the selection of the appropriate color would easily be accomplished by the ordinary artisan depending on the specific patient or patient population. For example, based on the teachings of Alexander one would be motivated to produce the unit dosages in the favorite color of a child (page 5, first paragraph), but Alexander also teaches that the flavor may be varied. Furthermore, Alexander teaches an orange-coated chocolate ball as an example of a suitable flavor combination (page 11, first paragraph). Thus, the artisan would understand that the flavor and color do not necessarily need to be those that are typically paired together. Based on these teachings, the artisan would readily envision any combination of colors and flavors, rendering claim 8 obvious.
- 7. Regarding claim 16, as discussed above, Thompson teaches the addition of scents to topical formulations. Thus, if an artisan wanted to administer a dosage regimen transdermally (i.e. percutaneously), for example the administration of nicotine, a one would be motivated to add a scent to the unit doses of the drug for the reasons

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described above. In this case, the transdermal dosage form is itself a fragrance dispenser, rendering claim 16 obvious.

8. Based on the teachings of Bernstein and Thompson presented above, the addition of scents to a dosage regimen to improve the acceptability to the patient would have been obvious to the skilled artisan. The particular placement of the fragrance, whether it be in the dosage form itself or in an external device that accompanies the treatment regimen is a matter of design choice. Bernstein teaches that odors are important factors in the development of taste and odor aversion, thus the artisan would recognize that an odor accompanying a dosage regimen would only need to be present in order to have an impact. The decision regarding where to place the odoriferous material would easily be made by the practitioner, rendering claim 17 obvious.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

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Claims 15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernstein in view of Thompson and Alexander as applied to claims 1-14, 16, and 17 above, and further in view of BIBERMAN (2002/0019421; Filed Jul. 5, 2001).

- 9. The teachings of Bernstein, Thompson, and Alexander are presented supra. The references do not explicitly describe the sequential or co-administration of both an oral dosage form and a parenteral dosage form (i.e. where a parenteral administration is accompanied by an oral administration). However, such would have been obvious to the skilled artisan. As stated above, it is well within the skill of the ordinary artisan to empirically determine the best flavors, colors, form, and route of administration in view of the specific patient to be treated, their particular condition, and the length of time required for the dosage regimen. This would include multiple routes of administration simultaneously as was known in the art at the time of the invention.
- 10. For example, Biberman discloses coadministration of a compound to treat addiction (e.g. monoamine oxidase inhibitors, MAOIs) along with the addictive agent (e.g. nicotine) in order to benefit from the combined effects of the two substances to wean the patient from addiction as well as reducing the adverse symptoms of withdrawal (abstract). Biberman teaches that a particularly preferred form of the invention includes both oral administration of the first component (i.e. MAOI) and transdermal administration of the second component (i.e. nicotine) (paragraphs [0038] and [0040]). Thus, if one wished to administer this type of drug regimen, one would be motivated to include various flavors, colors, and scents in either or both portions of the combination therapy in order to prevent taste/odor aversion and to make the regimen

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more acceptable to the patient as taught by Bernstein, Thompson, and Alexander, rendering claims 15 and 18 obvious.

Conclusion

No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KSO

/David J Blanchard/ Primary Examiner, Art Unit 1643